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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,086	07/25/2003	Robert Deziel	660081.443	3523

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EXAMINER

KHARE, DEVESH

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9-11-
Office Action Summary

Application No. 10/628,086	Applicant(s) DEZIEL ET AL.	
Examiner Devesh Khare	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 5-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>5/26/2004</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/5/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

Restriction is required under 35 U.S.C. 121:

- I. Claims 1-4 drawn to pyrimidine nucleosides of general structure (I) and their pharmaceutical composition, classified in classes 514, 536 and 424, subclass various.
- II. Claims 5-12, drawn to a method of treating or preventing a disease or condition associated with DNA or RNA processing enzymes (viral disease) with the composition of Group I, classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Groups **I to II** are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product can be practiced with another materially different product i.e. a method of treating viral disease can be practiced with a composition comprising 5'-amino acid esters of Ribavirin, see U.S. Patent 6,277,830.

Although the inventions are classified in the same class and sub-class, searching the two groups of inventions constitutes a burdensome search, as a thorough search comprises a search of foreign patents and non-patent literature as well as the

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appropriate U.S. patent classifications. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper. It is noted that examination of the two independent and distinct inventions would indeed impose an undue burden upon the examiner in charge of this application.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

(MPEP § 821.04)

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

A telephone call was made to Jeffrey Pepe on 5/26/04 to request an oral election to the above restriction requirements. During telephone conversation with Jeffrey Pepe on 5/26/04, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-4. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-4 are before the examiner and an action on the merits of said claims is contained herein below.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims **1-4** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) In all occurrences, in the absence of the chemical formula or name of "one or more amino acids" claimed, render the claims indefinite wherein applicant fails to articulate by chemical name or structural formula.

(B) In claim 1, in the absence of the chemical formula or name of "a heterocycle" claimed, render the claims indefinite wherein applicant fails to articulate by chemical name or structural formula.

(C) Claim 1 is vague and indefinite as it is unclear whether the term "amines or absent and linked via an alkene" is intended to be a Markush group.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-4 are rejected under 35 U.S.C. 103(a) as being obvious over claims Marx et al. (Marx) (EP 799 834) in view of Ganguly et al. (Ganguly) (U.S. Patent 6,277,830).

The instant invention is directed to the nucleosides of formula (I) and (II) and pharmaceutically composition thereof wherein R^1 in the carbohydrate moiety (at C-5) is OH, N-alkyl, one or more amino acids and R^5 in the pyrimidine moiety is OH, N_3 , H, halo, alkyl, alkoxy, or amine. Additional claim limitation include the nucleoside of structure III and a pharmaceutically acceptable carrier, diluent, or excipient.

Marx teaches nucleotide analogs of formula (2) useful for their antiviral activity (page 2, lines 25-35). Marx discloses the nucleoside analogs wherein R^2 in the carbohydrate moiety (at C-5) is mono-, di-, or triphosphate group and the pyrimidine moiety is uracil, thymine, cytosine, 5-chloro-,bromo- or fluoro-uracil, dihydrouracil or 5-methylcytosine (page 2, lines 45-55 and claim 1). Marx also discloses the pharmaceutically acceptable salts of acids and bases (page 3, lines 54-59). The pharmaceutical compositions are disclosed on page 4, lines 35-55). Marx differs from the applicant's invention that the nucleosides disclosed by Marx does not include amino acid substitution at C-5 in the carbohydrate moiety.

Ganguly teaches 5'-amino acid esters of ribavirin and their pharmaceutical compositions useful in treating viral infections (abstract). Ganguly discloses that 5' amino acid esters of ribavirin metabolizes in vivo into ribavirin and have produced higher plasma concentrations of ribavirin when compared to administration of ribavirin (col.8,

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lines 40-45). Ganguly also discloses various amino acid substituents of the ribavirin (col.18, Table 3).

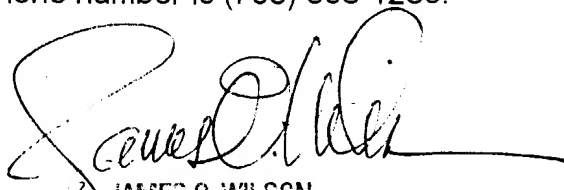
It would have been obvious to person having ordinary skill in the art at the time the invention was made, to modify the pyrimidine-nucleosides because Marx had disclosed that pyrimidine nucleosides have antiviral activity, in view of the recognition in the art, as evidenced by Ganguly, that discloses that the amino acid substitution at C-5' of a nucleoside is useful because the 5'-amino acid esters of ribavirin metabolizes in vivo into ribavirin and have produced higher plasma concentrations of ribavirin when compared to administration of ribavirin. The motivation is provided by Marx reference, the prior art suggests that nucleoside analogs have antiviral activity and can be used to treat AIDS or some sarcomas (page 2, lines 13-14).

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571) 272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD.
Art Unit 1623
August 6, 2004


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1000